

No. 23-5067

**United States Court of Appeals
for the District of Columbia Circuit**

**MEDICAL IMAGING & TECHNOLOGY ALLIANCE, ET AL.,
Plaintiffs - Appellants,**

v.

**LIBRARY OF CONGRESS, ET AL.,
Defendants - Appellees.**

On appeal from a final judgment of the
United States District Court for the District of Columbia
Case No. 22-cv-499 (BAH)

APPELLANTS' OPENING BRIEF

PETER TOLSDORF

*National Electrical
Manufacturers Association
1300 17th Street North, No. 900
Arlington, VA 22209
(703) 841-3200*

*Counsel for Medical Imaging &
Technology Alliance*

MICHAEL B. KIMBERLY

*ALEX C. BOOTA
EMMETT WITKOVSKY-ELDRED
McDermott Will & Emery LLP
500 N. Capitol Street NW
Washington, DC 20001
mkimberly@mwe.com
(202) 756-8000*

Counsel for appellants

TERRY CHANG

*Advanced Medical
Technology Association
1301 Pennsylvania Ave. NW
Suite 400
Washington, DC 20004
(202) 783-8700*

*Counsel for Advanced Medical
Technology Association*

**CERTIFICATE AS TO PARTIES,
RULINGS, AND RELATED CASES**

Parties and amici. The parties before the Court are appellants Medical Imaging & Technology Alliance (MITA) and Advanced Medical Technology Association (AdvaMed); and appellees the Library of Congress and Carla Hayden, in her official capacity as Librarian of Congress.

Rulings under review. The ruling under review is *MITA v. Library of Congress*, No. 1:22-cv-499, Dkt. 26 (Mar. 7, 2023).

Related cases. This case has not previously been before this Court, and there are no related cases currently pending in this or any other court.

/s/ Michael B. Kimberly

CORPORATE DISCLOSURE STATEMENT

The Medical Imaging & Technology Alliance is a division of the National Electrical Manufacturers Association (NEMA), which is a non-profit trade association. No publicly held corporation owns an interest in MITA or NEMA.

The Advanced Medical Technology Association is a non-profit trade association that represents the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. It has no parent corporation. No publicly held corporation owns an interest in AdvaMed.

/s/ Michael B. Kimberly

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GLOSSARY

APA – Administrative Procedure Act

DMCA – Digital Millennium Copyright Act

FDA – Food & Drug Administration

ISO – independent service operator

NPRM – notice of proposed rulemaking

OEM – original equipment manufacturer

INTRODUCTION

The Administrative Procedure Act entitles anyone “adversely affected or aggrieved by agency action” to obtain “judicial review thereof.” 5 U.S.C. § 702. This appeal presents a question not previously resolved by the Court: whether, pursuant to that language, persons aggrieved by a regulation promulgated by the Library of Congress under the Digital Millennium Copyright Act, using notice-and-comment rulemaking, are entitled to judicial review thereof.

They are. The APA provides for review of any final action of an “agency.” 5 U.S.C. §§ 702, 704. It defines an “agency” as any “authority of the Government of the United States,” excluding “the Congress,” among other exceptions not here relevant. *Id.* § 701(b)(1). The district court below held that the Library is not an “agency,” and thus that its actions are never reviewable under the APA, because it is categorically a component of “the Congress.”

That is wrong. The Library is in fact a hybrid entity that acts sometimes as a part of “the Congress” and sometimes as an “agency” within the Executive Branch. This Court has suggested so itself, describing the Library as “a free-standing entity” that is not categorically located within either of the political branches. *Intercollegiate Broadcasting System v. Copyright Royalty Board*, 684 F.3d 1332, 1341 (D.C. Cir. 2012). In many circumstances, it plays a legislative role and is better understood as a “congressional agency.” *Id.* But in other circumstances, such as when it “promulgate[s] copyright regulations,” it

exercises purely executive power and “is undoubtedly a ‘component of the Executive Branch.’” *Id.* at 1342 (quoting *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 511 (2010)). It stands to reason that when the Library is fulfilling an executive rulemaking role and thus operating as a component of the Executive Branch, it qualifies as an “authority of the Government of the United States” that is *not* a part of “the Congress.” 5 U.S.C. § 701(b)(1).

This conclusion finds powerful support in the language of the relevant statutes. The DMCA expressly directs the Library to engage in a “rulemaking,” which is a purely executive function that (according to the APA) only an “agency” may perform. *See* 5 U.S.C. §§ 551(5), 553. And when the Library performs this function, it utilizes tools like the Federal Register and Code of Federal Regulations that (according to the Federal Register Act) only an “agency” may use. *See* 44 U.S.C. §§ 1501, 1510. The Library’s status as an “agency” is confirmed yet further by the relevant canons of construction, including the presumption in favor of judicial review, which calls for a narrow interpretation of review-limiting words like “the Congress.”

The Court’s precedents are not to the contrary. To be sure, the Court held in *Clark v. Library of Congress* that the Library did not qualify as an “agency” in that case. 750 F.2d 89, 102 (D.C. Cir. 1984). But it reached that conclusion in a single, unexplained sentence, issued in the context of an employment dispute. Courts uniformly agree that the Library does not function as a component of the

Executive with respect to its personnel decisions. *Clark* thus did not involve, and could not have answered, the question whether the Library is an “agency” when engaging in executive rulemakings.

Even if all that we have said were wrong, however, the Court still would have to reverse under *Larson v. Domestic & Foreign Commerce Corporation*, 337 U.S. 682 (1949). The rulemaking at issue here plainly exceeded the Library’s statutory authority. By either path, the Court should reverse and remand for resolution of appellants’ claims on their merits.

JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1331 and entered an appealable final judgment on March 7, 2023. JA33-34. Appellants filed a timely notice of appeal on March 24, 2023. JA5. This Court’s jurisdiction rests on 28 U.S.C. § 1291.

ISSUES PRESENTED FOR REVIEW

1. Whether a regulation promulgated by the Library of Congress under Section 1201 of the DMCA, using notice-and-comment rulemaking procedures, is reviewable in federal court as a final “agency” action under the APA’s judicial review provision (5 U.S.C. § 702).
2. Whether, alternatively, the Librarian of Congress acted sufficiently in excess of her statutory or constitutional authority in this case to warrant equitable relief under the *Larson* doctrine.

STATUTES AND REGULATIONS

The relevant statutory provisions are set out in an addendum to this brief.

STATEMENT OF THE CASE

A. Statutory background

The Administrative Procedure Act. The APA “governs the proceedings of administrative agencies and related judicial review.” *Allentown Mack Sales & Service, Inc. v. N.L.R.B.*, 522 U.S. 359, 374 (1998) (quotation marks omitted). It thus defines the “rule making” processes that executive agencies must undertake to implement statutes assigned to them by Congress. 5 U.S.C. § 553. Chief among these procedures is notice and comment, which involves a “notice” of proposed rulemaking “published in the Federal Register,” followed by “interested persons [having] an opportunity to participate” at hearings and through submission of written comments. *Id.*

In addition to establishing the familiar notice-and-comment procedures, the APA “provides for judicial review of agency action[s]” promulgated using those procedures. *Schindler Elevator Corp. v. WMATA*, 16 F.4th 294, 301 (D.C. Cir. 2021). It thus specifies that any “person suffering legal wrong because of agency action” or who is “adversely affected or aggrieved by agency action” may obtain “judicial review thereof.” 5 U.S.C. § 702.

To be judicially reviewable under the APA, an action must be one of an “agency.” The APA in turn defines an *agency* as “each authority of the Govern-

ment of the United States . . . but does not include,” as relevant here, “the Congress.” 5 U.S.C. § 701(b)(1).

By amendment adopted in 1976 (see Pub. L. 94-574, § 1 (Oct. 21, 1976), 90 Stat. 2721), the APA’s judicial review provision further waives the sovereign immunity of the United States. It thus provides that suits for nonmonetary relief challenging federal agency action or inaction “shall not be dismissed nor relief therein be denied on the ground that it is against the United States.” 5 U.S.C. § 702. As this Court “repeatedly” has explained, “[t]here is nothing in the language of the second sentence of § 702 that restricts its waiver [of immunity] to suits brought under the APA.” *Trudeau v. FTC*, 456 F.3d 178, 186 (D.C. Cir. 2006). Thus, “the APA’s waiver of sovereign immunity applies to any suit” challenging a final agency action, “whether [it is brought] under the APA or not.” *Id.* (quotation marks omitted) (quoting *Chamber of Commerce v. Reich*, 74 F.3d 1322, 1328 (D.C. Cir. 1996)).

The Federal Register Act. Congress enacted the Federal Register Act shortly before the APA. *See* Pub. L. 74-220 (July 25, 1935), 49 Stat. 500. The Federal Register Act requires the Government Publishing Office to establish a “serial publication designated the ‘Federal Register.’” 44 U.S.C. § 1504. Only a statutorily defined “document” may be published in the Federal Register. *Id.* § 1505. No notice or final rule constitutes a “document” unless it is issued by the President or “promulgated by a Federal agency.” *Id.* § 1501.

The Federal Register Act further provides for the printing of a permanent “supplement” to the Federal Register called “the Code of Federal Regulations.” 44 U.S.C. § 1510(a), (b). The Code of Federal Regulations shall contain the “complete codifications of the documents of each agency of the Government having general applicability and legal effect” and adopted “in the discharge of, its activities or functions.” *Id.* § 1510(a). Only “documents of the several agencies” may appear in the Code. *Id.* § 1510(e).

The Federal Register Act defines an “agency” in relevant part as a component “of the administrative branch of the Government of the United States but not the legislative or judicial branches of the Government.” 44 U.S.C. § 1501. According to the APA’s legislative history, “the term ‘agency’ was supposed to have substantially the same meaning in the APA as” it was given nine years earlier in the Federal Register Act. *Washington Legal Foundation v. U.S. Sentencing Commission*, 17 F.3d 1446, 1449 (D.C. Cir. 1994). Consistent with that observation, the Administrative Committee of the Federal Register—which is tasked by Congress with implementing the Federal Register Act—has defined “agency” under the Federal Register Act as materially identical to its definition under the APA. *See* 1 C.F.R. § 1.1.

The Digital Millennium Copyright Act. Congress enacted the DMCA near the end of the Twentieth Century, at the advent of the Internet. Around this time, many copyright owners began using “technological protective measures”

to control access to their digital creations. These measures included various encryption tools and password protection.

To “strengthen copyright protection in the digital age” (*Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 435 (2d Cir. 2001)), the DMCA prohibits users of copyrighted works from “circumvent[ing] a technological measure that effectively controls access to [the] work.” 17 U.S.C. § 1201(a)(1)(A). To circumvent a technological protective measure is to “descramble” or “decrypt” a work, and otherwise to “avoid, bypass, remove, deactivate, or impair [a technological protective measure], without the authority of the copyright owner.” *Id.* § 1201(a)(3). The DMCA’s anticircumvention rule is enforceable through private civil remedies, and in the case of a willful violation “for purposes of commercial advantage or private financial gain,” through criminal penalties. *Id.* § 1204(a).

Congress did not intend for the DMCA to inhibit noninfringing uses of digital works, however. It therefore authorized the Library of Congress, upon the recommendation of the Register of Copyrights, to grant selective waivers of the anticircumvention rule “if necessary to prevent a diminution in the availability to individual users of a particular category of copyrighted materials” for noninfringing uses. 17 U.S.C. § 1201(a)(1)(C).

The DMCA instructs the Librarian to grant exemptions “in a rulemaking proceeding” on a recurring basis, every three years. 17 U.S.C. § 1201(a)(1)(C).

The Library's triennial rulemaking under Section 1201(a)(1)(C) follows the notice-and-comment requirements of Section 553 of the APA. It thus commences with a notice of inquiry published in the Federal Register in the name of the U.S. Copyright Office and the Library of Congress. *See, e.g.*, JA67-71. Proponents of exemptions then file petitions and supporting evidence on the regulatory docket.

The Library and Copyright Office next publish in the Federal Register a notice of proposed rulemaking (NPRM) with the proposed exemptions. *See, e.g.*, JA72-89. The NPRM is subject to staged comments from proponents and opponents of the proposed exemptions. The Copyright Office also holds a public hearing. *See, e.g.*, JA90-91.

At the conclusion of the notice-and-comment process, the Register of Copyrights prepares a comprehensive recommendation concerning the proposed exemptions and submits it to the Librarian. *See, e.g.*, JA135-178. The Librarian in turn adopts a final rule published in the Federal Register, again in the name of the Library and Copyright Office. *See, e.g.*, JA92-106. The exemptions are then codified in the Code of Federal Regulations, at 37 C.F.R. § 201.40(b).

B. Factual background

This case concerns a challenge by the Medical Imaging & Technology Alliance and Advanced Medical Technology Association to a DMCA exemption promulgated by the Library and codified at 37 C.F.R. § 201.40(b)(15).

1. Advanced medical devices like MRI machines, CT scanners, surgery-assisting robots, and defibrillators have transformed patient care by enabling healthcare providers to diagnose disease accurately and promptly, and by assisting treatment. The manufacturers of these devices—known as “original equipment manufacturers” or OEMs—create innovative computer code that allows these highly complex machines to function safely and effectively.

Like any other creative work, this software is protected by copyright. *See* 17 U.S.C. §§ 101, 102(a). OEMs use a variety of technological protective measures, including encryption, to guard against unauthorized access to and copying of their copyrighted software. JA15 (Compl. ¶ 39). These limits not only safeguard OEMs’ intellectual property but also ensure the privacy of patient data and that only appropriate users operate medical device software. JA15-17 (Compl. ¶¶ 39, 44-45). For example, OEMs license to healthcare providers the clinical software they need to treat patients, and they use technological protective measures to ensure that only authorized providers have access. JA16-17 (Compl. ¶¶ 44-45). In short, technological protective measures are vital to securing the integrity of medical devices, thereby enhancing cybersecurity and their safe functioning for patients.

Evaluation, maintenance, and repair of complex medical devices requires accessing and copying computer code designed to diagnose machine malfunctions. JA16, 19 (Compl. ¶¶ 41-42, 55). Improper use of this software for

servicing medical devices introduces substantial risks to its owners and users, including injury like electrical shock or overexposure to radiation, and delayed or misinformed medical diagnoses. JA16-17 (Compl. ¶¶ 44-45). For this reason and others, the Food and Drug Administration (FDA) strictly regulates OEMs, requiring agency approval before OEMs may market certain devices (21 C.F.R. Parts 801, 814) and imposing device service and maintenance requirements for quality control purposes (21 C.F.R. Part 820).

2. Independent service operators (ISOs) provide unregulated third-party medical device maintenance and repair services. JA16, 18 (Compl. ¶¶ 42, 49-50). They are not subject to the same FDA regulations that apply to OEMs, including training and quality control requirements. JA17 (Compl. ¶ 47). Many OEMs authorize ISOs to perform basic maintenance and repair, sometimes by granting limited licensing of copyrighted documentation and software. JA18 (Compl. ¶ 51). But some ISOs routinely attempt to circumvent OEMs' technological protective measures to gain unauthorized access to copyrighted diagnostic software to market advanced maintenance services. JA18 (Compl. ¶ 50). This allows ISOs to freeride on manufacturers' innovations without internalizing any research-and-development costs. *Id.*

Circumventing technological protective measures in medical devices can produce software vulnerabilities. JA16-17 (Compl. ¶ 45). Such vulnerabilities, which may impair the machine's functionality and compromise private patient

information, “have the potential to result in patient illness, injury, or death.” *FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices* (May 2018), at 25. Accordingly, the FDA recommends that OEMs “limit[] privileged access to operating systems and applications” and restrict “software or firmware updates to authenticated code only.” *Id.*

3. In the eighth and most recent triennial DMCA rulemaking, two ISOs petitioned for an exemption to access medical device software and data files for purposes of diagnosis, maintenance, and repair. *See JA179-185.* Though they claimed that such access was “fair use,” they asserted no interest other than to facilitate their for-profit business objectives. *See JA180, 183.*

The Library and Copyright Office published an NPRM identifying seventeen proposed exemptions, including the exemption sought by the ISOs. JA72-89. The Library did not describe the proposed exemption but “invit[ed] comment on the extent to which its prior analysis of” exemptions for third-party service providers in other contexts “may be applicable here.” JA86.

Appellants and at least one of their mutual members submitted comments opposing the proposed exemption, arguing that it served purely commercial, non-transformative purposes that were not fair use; and that granting it would offend the basic purposes of the copyright laws. *See generally JA215-291.*

The Register nonetheless recommended granting an exemption covering “[c]omputer programs that are contained in and control the functioning of a

lawfully acquired medical device or system, and related data files.” JA178. We refer to this as the Exemption, which shields ISOs from DMCA liability when they circumvent technological protective measures if “necessary . . . to allow the diagnosis, maintenance, or repair of such a device or system.” *Id.*

Addressing the fair use question, the Register stated without explanation that “[c]ommerciality is not fatal to a fair use determination” and “that proponents’ proposed use is likely transformative and so the first factor favors fair use.” JA154. That transformative-use finding contradicted the Register’s own prior acknowledgement that the ISOs themselves had not claimed transformative use insofar as they did “not seek an exemption to *modify* medical devices or systems, or their software.” JA153 (emphasis added). The ISOs likely did not request an exemption to modify code because FDA guidance suggests that modifying medical-device system software, even just for maintenance and repair, is likely to constitute device “remanufacturing,” which would be subject to extensive FDA reporting and registration requirements. *See* FDA Center for Devices and Radiological Health, *Remanufacturing of Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff*, perma.cc/M3Q9-WF8C (June 21, 2021); *see also* 21 C.F.R. § 820.3(w); JA174.

The Register further opined that medical-device system software is entitled to diminished copyright protection because it is “not used for [its] expressive qualities, but rather for [its] functional and informational aspects

that enable users to control and understand the operation of the equipment.” JA155. The Register also concluded that ISOs’ copying of the entirety of OEMs’ works “should be given little weight here because the use is necessary to accomplish the transformative purposes of diagnosis, maintenance, and repair.” JA156. Again, that conclusion was contradicted by the Register’s observation that the ISOs did “not seek an exemption to *modify* medical devices or systems, or their software.” JA153 (emphasis added).

After addressing the Section 1201(a)(1)(C) factors in cursory fashion (see JA171-172), the Register turned to extra-statutory economic considerations. She observed that OEMs typically “charge higher prices” than ISOs for medical-device maintenance and repair, and therefore “medical service providers must spend more to service their equipment” if they use OEM services “than if they were able to engage in self-repair or have an ISO perform repairs on their behalf.” JA173. Without acknowledging that the point of copyright law is to ensure that competitors who do not bear the costs of creation cannot copy works to undercut prices, the Register opined that granting the Exemption would “help to address the broader competitive concerns recently highlighted by the Executive Branch” concerning repair and maintenance. *Id.* On that ground, she recommended adopting the Exemption.

The Librarian adopted the Exemption “based upon the Register’s Recommendation” without further explanation. JA92.

The Exemption is codified at 37 C.F.R. § 201.40(b)(15).

C. Procedural background

Appellants MITA and AdvaMed filed a complaint for declaratory and injunctive relief, alleging that the promulgation of the Exemption was arbitrary and capricious and not in accordance with law (JA27-28 (Compl. ¶¶ 78-85)) and adopted without observance of required procedures (JA29 (Compl. ¶¶ 86-91)). In the alternative, they pleaded claims pursuant to the *Larson* doctrine, alleging that the Librarian’s actions were *ultra vires* because they exceeded her statutory authority and violated the Constitution. JA29-31 (Compl. ¶¶ 92-101).

Appellants moved for summary judgment, and the Library cross-moved to dismiss or, in the alternative, for summary judgment. The district court denied appellants’ motion and granted the government’s cross-motion. JA33. It held that sovereign immunity bars all of plaintiffs’ claims.

Concerning the APA, the district court held (JA52) that because the Library “is indisputably part of Congress,” it never qualifies as an “agency” under the APA. As the district court saw it (*id.*), the APA’s “plain text” resolved the issue. But in purporting to answer that question, the court did not address the DMCA’s or Federal Register Act’s text.

The district court further held that “binding D.C. Circuit precedent makes [it] crystal clear” that the Library is categorically exempted from judicial review under the APA. JA53 (citing *Clark*, 750 F.2d at 102-103; *Ethnic Employees of*

Library of Congress v. Boorstin, 751 F.2d 1405, 1416 n.15 (D.C. Cir. 1985); *Washington Legal Foundation*, 17 F.3d at 1449).

Having rejected appellants' APA claims, the district court ruled next that appellants had failed to state a claim under *Larson*. It concluded (JA61) that any error in the Librarian's fair-use analysis was "nothing more than a textbook error in statutory interpretation," and thus, in its view, the Librarian had not exceeded any specific statutory command. The district court reasoned also (JA64) that the Library's exercise of executive authority under the DMCA does not violate the separation of powers because the Library is a hybrid entity that may exercise legislative or executive authority so long as it does not do both "simultaneously." The district court did not attempt to reconcile that conclusion with its holding that the Library is categorically a component of "the Congress" under the APA.

SUMMARY OF ARGUMENT

I. The Library's triennial DMCA rulemakings are subject to judicial review under the APA because, as a matter of both statutory text and precedent, the Library functions as an "agency" within the meaning of the APA when it is engaged in its executive "rulemaking" role. As the Court explained in *Inter-collegiate*, the Library is a hybrid agency. When it is conducting executive business, such as when it implements statutes entrusted to it by Congress, the Library is irrefutably a component of the Executive Branch. And if it is acting as

a component of the Executive Branch, it stands to reason that it does not qualify as a part of “the Congress” for purposes of the APA.

This conclusion is confirmed by the relevant statutory text. To begin, the DMCA instructs the Library to engage every three years in a “rulemaking.” That is a term of art under the APA—it refers to the traditional notice-and-comment process by which agencies propose, test, and adopt formal regulations that are ultimately published in the Code of Federal Regulations. And it is a process that may be undertaken, according to the APA, only by an “agency.” By tasking it with “rulemaking” responsibilities, then, Congress was signaling that it understands the Library to qualify as an “agency” whose executive functions are covered by the APA.

The Federal Register Act confirms the same. Consistent with the DMCA’s instruction, the Library utilizes the APA’s rulemaking procedures, including by publishing all notices in the Federal Register and codifying its final DMCA exemptions in the Code of Federal Regulations. Under the Federal Register Act, these are things that, once again, only an “agency” may do. And critically, the Federal Register Act defines an “agency” the same way, substantively, as does the APA. It hardly could be otherwise, given the tight interconnectedness of the two statutes.

The district court was wrong to conclude that a holding for appellants here would render superfluous the statutory provision subjecting the Copyright

Office’s actions to judicial review under the APA. Our position with respect to the Library is that only its purely executive actions—most clearly including its notice-and-comment rulemakings—are subject to judicial review under the APA. But that leaves the bulk of the Library’s actions, including any undertaken in its day-to-day operations, free from judicial supervision. Not so of the Copyright Office, *all* decisions of which are judicially reviewable. No statutory provision would be made inoperable by a ruling for appellants here.

The relevant canons of construction resolve any ambiguity on these points in favor of reversal. To begin with, the canon in favor of judicial review requires Congress to provide a clear statement before a statute may be construed to divest the courts of their traditional supervisory role over the Regulatory State. There is no such clear statement here. On the contrary, the Library, acting in an executive role, cannot constitute a component of “the Congress” within the meaning of the APA. At the very least, the answer to that question is arguable, requiring resolution in favor of judicial review.

The canon of constitutional avoidance also favors reversal. Under that canon, the Court must, if it can, avoid the constitutionally unacceptable conclusion that the Library is a congressional agency that exercises executive authority. There are two ways for the Court to do so. *First*, it can hold that the Library is a component of “the Congress” within the meaning of in the APA, but that the APA’s text refers not to the legislative branch established by

Article I of the Constitution, but rather to some imaginary, undefined entity that happens to be labeled “the Congress” but which includes executive offices that may exercise executive power. That would make no sense. *Alternatively*, the Court can avoid the constitutional problem by holding that the words “the Congress” in the APA refer to “the Congress” in the Article I sense (obviously they do), and that the Library, when it exercises executive power, is not an element of “the Congress” within the meaning of the APA. Only the second option makes sense because it gives the words “the Congress” their only plausible meaning.

Finally, a holding that the Library is an “agency” with respect to its DMCA rulemakings would be consistent with the Court’s precedents. True, the Court held more than forty years ago, in a single sentence in *Clark*, that the Library is not an “agency” within the meaning of the APA. But *Clark* concerned a routine employment decision, which is a part of the Library’s day-to-day operations and thus not, in our view, subject to APA review. Court opinions must be read in light of, and limited to, their facts. The question whether the Library qualifies as an “agency” under the APA when it is engaged in notice-and-comment rulemaking was not a question presented in or resolved by *Clark*. It thus remains an open issue, which the Court may answer in favor of appellants without calling *Clark* into question.

II. Alternatively, the Court should reverse under the *Larson* doctrine, which provides relief for *ultra vires* government actions.

Review for *ultra vires* acts rests on the longstanding principle that if an agency action is unauthorized by the statute under which the agency assumes to act, the courts generally have jurisdiction to grant relief. That describes the circumstances here exactly. The DMCA authorizes the Librarian to grant exemptions from the anticircumvention rule to protect noninfringing uses of the copyrighted material. But in granting the Exemption, the Librarian effectively disregarded that requirement. Although she invoked the fair-use factors in name, she in fact brushed aside critical legal and factual barriers to finding the exempted uses to be “fair” ones.

Most obviously, the proposed uses at issue here are purely commercial, which counts strongly against a fair-use finding. The Librarian discounted that consideration entirely, supposedly on the ground that the proposed uses are “transformative,” and thus independently creative. Such a finding is utterly unsupported here—in fact, the ISOs seeking the Exemption expressly disclaimed transformative use, because to modify the computer code at issue would risk triggering FDA regulation.

The Librarian’s fair-use analysis is so out of step with the facts and the law that it cannot reasonably be called a fair-use analysis at all. And at the conclusion of her rulemaking, the Librarian revealed the true reason for the

Exemption: economic policymaking that is unauthorized by the DMCA. The Librarian reasoned in particular that to grant the Exemption would help lower prices and improve competition in the market for repair services. But that literally turns the purpose of copyright, which is to *protect* the commercial rights of creators, on its head. In this way, the Librarian used her DMCA rulemaking to advance policies that are at odds with the copyright principles that Congress expressly embedded in the statute. The Exemption is thus *ultra vires* and should be vacated even if the APA does not apply.

STANDARD OF REVIEW

The Court reviews *de novo* the district court’s grant of a motion to dismiss under Rule 12(b)(1) or Rule 12(b)(6). *See, e.g., Kim v. United States*, 632 F.3d 713, 715 (D.C. Cir. 2011).

ARGUMENT

I. THE LIBRARY’S TRIENNIAL DMCA RULEMAKINGS ARE SUBJECT TO JUDICIAL REVIEW UNDER THE APA

This appeal can be resolved straightforwardly by confirming that the Library qualifies as an “agency” (that is to say, it is not a part of “the Congress”) within the meaning of the APA when it engages in an executive rulemaking that conforms with the APA’s notice-and-comment procedures. In its formal rulemaking role, this Court has said, the Library is “undoubtedly a ‘component of the Executive Branch.’” *Intercollegiate*, 684 F.3d at 1342. In

that role, the Library therefore falls within the APA's definition of an "agency."

On this ground alone, the Court can and should reverse and remand to the district court for resolution of the merits of appellants' APA claims.

A. The Library functions as an "agency" within the meaning of the APA when playing an executive "rulemaking" role

The judgment below rests on the faulty premise that because the Library of Congress functions as a component of "the Congress" in *some* circumstances, it is excluded from the APA's definition of an "agency" in *all* circumstances, regardless whether the challenged action is a purely executive function that cannot actually be performed by "the Congress." That premise, offered below as mere *ipse dixit*, is not sustainable.

1. *The Library does not qualify as "the Congress" when it is engaged in executive rulemakings*

a. The analysis begins on common ground among the parties: The Library is a hybrid entity, sometimes functioning as a component of the Congress and sometimes as a component of the Executive Branch.

This Court has said so in express terms. In certain respects, the Library performs "functions . . . that are exercised primarily for legislative purposes," such as when it performs its work collecting, analyzing, and disseminating data through "the Congressional Research Service." *Intercollegiate*, 684 F.3d at 1341. In that role and others like it, the Library is properly understood as a

“congressional agency.” *Id.* (quoting *Keeffe v. Library of Congress*, 777 F.2d 1573, 1574 (D.C. Cir. 1985)).

But in other respects, the Court has recognized, the Library performs purely executive functions. Notably, “the Librarian is appointed by the President” and “is subject to unrestricted removal by the President.” *Inter-collegiate*, 684 F.3d at 1341 (citing 2 U.S.C. § 136; *Ex parte Hennen*, 38 U.S. (13 Pet.) 230, 259 (1839)). That being so, the Library is invested with and sometimes exercises quintessentially executive “powers,” including those “to promulgate copyright regulations” and “to apply the statute to affected parties.” *Id.* When it is acting in this law-implementing role, “the Library is undoubtedly a ‘component of the Executive Branch.’” *Id.* at 1342.

The APA’s text is entirely capable of accommodating the hybrid character of the Library, treating it as an “agency” in some circumstances but not others. It follows that, when the Library is performing traditionally executive functions (such as when it promulgates regulations that implement statutes it has been tasked with executing), it assumes the status of an “agency”; and when it is performing traditionally legislative functions (such as when it collects, analyzes, and disseminates information through the Congressional Research Service), it assumes the status of “the Congress.”

This approach best respects Congress’s intent, which was to “avoid a formalistic definition of ‘agency’ that might exclude any authority within the

executive branch that should appropriately be subject to the requirements of the APA.” *Armstrong v. Bush*, 924 F.2d 282, 289 (D.C. Cir. 1991). That describes the Library in the context of this case.

And it is easily implemented. To decide the capacity in which the Library is acting, courts must simply “consider each [of its] function[s] . . . separately and . . . determine the character of each, whether legislative or executive.” *Eltra Corp. v. Ringer*, 579 F.2d 294, 301 (4th Cir. 1978). Again, nothing in the statutory language forecloses this approach, which reconciles the APA’s text with the Library’s “hybrid character.” *Id.* And to hold otherwise would mean, implausibly, that the APA’s drafters intended the words “the Congress” to preclude judicial review of administrative rulemakings that, by definition, cannot constitutionally be performed by “the Congress.”

b. Neither the Library nor the district court grappled with this basic point in the proceedings below. For its part, the district court recognized that “[t]he Library serves both executive and legislative functions,” and that the Library “engages in executive power under Article II when promulgating rules under the DMCA.” JA64. But it concluded nonetheless—and without a word of further explanation—that “[t]he Library of Congress is indisputably part of Congress,” and therefore it “is excluded from the definition of an ‘agency’” in all cases, no matter the function it is performing. JA52.

This unexplained conclusion misses the point: Although the Library “indisputably is part of Congress” in *some* cases (JA52), so too it “undoubtedly [is] a ‘component of the Executive Branch’” in *other* cases (*Intercollegiate*, 684 F.3d at 1342). The question presented is how the Library should be treated under the APA when it is functioning as a component of the Executive Branch. Again, given its “hybrid character” (*Eltra*, 579 F.2d at 301), there is no reason to think the Library cannot assume the status of an “agency” in some circumstances while shedding it in others, so that some of its actions are subject to APA review and others are not. Only that conclusion respects Congress’s well recognized desire to “confer[] agency status on *any* administrative unit with substantial independent authority” in the exercise of executive functions. *Partington v. Houck*, 723 F.3d 280, 289 (D.C. Cir. 2013) (emphasis added).

2. *The Library’s use of notice-and-comment rulemaking indicates that the APA’s judicial review provision applies*

The Library’s status as an “agency” under the APA when it is engaged in the triennial DMCA rulemakings is confirmed by the statutory text and its unbroken practice of using of the APA’s Section 553 rulemaking procedures.

a. As an initial matter, the DMCA’s direction that the Library engage in a “rulemaking” indicates that Congress intended the APA to apply. The concept of a “rule making” is one governed by the APA, which defines it as a process that commences with a “notice . . . published in the Federal Register,” followed

by “an opportunity [for the public] to participate in the rule making through submission of written data, views, or arguments.” 5 U.S.C. § 553. Critically, a “rule making” is something that only an “agency” may do. *Id.* § 551(5). And it is by definition subject to judicial review. *Id.* §§ 551(13), 701(b)(2), 702.

Congress’s use of the word “rulemaking” in the DMCA must be understood as a reference to the traditional “rule making” defined by the APA.¹ “[W]here Congress borrows [a] term[] of art” like this, the Court must presume that it “knows and adopts the cluster of ideas that were attached” to it at the time of enactment, including “the meaning its use will convey to the judicial mind.” *Morissette v. United States*, 342 U.S. 246, 263 (1952). Or, to put it another way, “[w]hen a statutory term is obviously transplanted from another legal source,” as the word *rulemaking* in the DMCA was transplanted from the APA, “it brings the old soil with it.” *See Taggart v. Lorenzen*, 139 S. Ct. 1795, 1801 (2019) (quotation marks omitted).

In short, by tasking the Library with a “rulemaking,” Congress intended that the Library would use the APA’s notice-and-comment procedures, and, by extension, that the Library’s triennial adoption of DMCA exemptions would be subject to judicial review under Section 702 as an “agency” action.

¹ The APA’s use of a space in “rule making” does not indicate a different meaning from the word appearing without a space in the DMCA. *See, e.g.*, 5 U.S.C. § 562(11) (specifying that “‘rulemaking’ means ‘rule making’”).

b. This conclusion is confirmed beyond fair-minded dispute by the Federal Register Act. Since the DMCA was enacted in 1998, the Library has in fact always used Section 553 notice-and-comment procedures when adopting Section 1201 exemptions—it publishes all relevant documents in the Federal Register, takes and responds to comments, and promulgates the final exemptions in the Code of Federal Regulations.

Pursuant to the Federal Register Act, only an “agency” is authorized to do these things. The Act allows only “documents” to be published in the Federal Register (44 U.S.C. § 1505), which it defines to include “Presidential proclamations and Executive orders” along with any “order, regulation, rule . . . promulgated *by a Federal agency*” (*id.* § 1501 (emphasis added)). And it reserves the Code of Federal Regulations for the codification of “documents of [an] agency . . . promulgated by the *agency* by publication in the Federal Register.” *Id.* § 1510(a) (emphasis added).

Thus, with respect to its DMCA rulemakings, the Library is undeniably functioning as an “agency” within the meaning of the Federal Register Act. And under that Act, an “agency” is a government office that is a component “of the administrative branch . . . *but not the legislative or judicial branches.*” 44 U.S.C. § 1501 (emphasis added). Thus, when it is engaged in DMCA rulemakings, the Library is necessarily *not* a component of the “legislative . . . branch[]” for purposes of the Federal Register Act. *Id.*

That ought to resolve this appeal. When the 79th Congress enacted the APA nine years after the Federal Register Act, the Senate Report stated expressly that “[t]he term ‘agency’ [in the APA] is defined substantially as [it is] in . . . the Federal Register Act.” *Administrative Procedure Act, Legislative History 79th Cong., 1944-46*, S. Doc. No. 248, at 12 (1946) (quoted approvingly in *Washington Legal*, 17 F.3d at 1449). And that makes sense, given that the APA’s rulemaking procedures (5 U.S.C. § 553) depend inextricably on the Federal Register and Code of Federal Regulations.

Given this history and the interlocking functions of the two statutes, it is inconceivable that Congress would have intended the Library to constitute an “agency” rather than a component of the “legislative” branch for purposes of the Federal Register Act (44 U.S.C. § 1501), while not also intending it to constitute an “agency” rather than a component of “the Congress” for purposes of the APA (5 U.S.C. §§ 551(1), 701(b)(1)). Any doubt on that front is resolved by the Federal Register Act’s implementing regulations, which clarify that the word “agency” under the Federal Register Act bears a virtually identical meaning to the APA’s definition. *See* 1 C.F.R. § 1.1.

As a matter of statutory text and structure, therefore, when the Library undertakes its triennial DMCA rulemakings, it engages in a purely executive function that (according to the APA) only an “agency” may perform, utilizing tools that (according to the Federal Register Act) only an “agency” may use.

And more generally, the fact that the Library always has “been thought to have to comply with APA rulemaking procedures when issuing” its DMCA exemptions is powerful evidence that Congress intended it to be subject to the APA’s “judicial review provisions” as well. *Armstrong*, 924 F.2d at 289.

c. The district court declined to address these arguments, brushing them aside as inapposite in an unreasoned, single-sentence footnote. *See JA55*. The district court’s refusal to engage these points is unsupported.

For its part, the government did not deny in its briefing below that the Library utilizes Section 553 rulemaking procedures or that it thereby acts as an “agency” within the meaning of the Federal Register Act. Its only response was to say, without elaboration, that “it is conceivable that Congress could have intended ‘legislative branch’ and ‘the Congress’ to have different meanings.” MSJ Opp. 22 (alterations incorporated). But that makes no sense. As the Court held in *Washington Legal Foundation*, the APA’s carveout for “the courts of the United States” must be read as coextensive with the Federal Register Act’s carveout for “entities within the judicial branch.” 17 F.3d at 1449. So too here: The APA’s carveout for “the Congress” (5 U.S.C. § 701(b)(1)) is of course coextensive with the Federal Register Act’s carveout for the “legislative . . . branch[]” (44 U.S.C. § 1501). Thus, as a matter of the text and structure of the APA, Federal Register Act, and DMCA, the Library is an “agency” when it is engaged in notice-and-comment rulemaking under DMCA Section 1201.

3. ***17 U.S.C. § 701(e) does not alter the analysis***

Congress’s express decision in 17 U.S.C. § 701(e) to make the Copyright Office, which is a component of the Library, subject to the APA does not undermine this textual analysis. According to the district court, to hold that the Library’s DMCA rulemakings are subject to judicial review under the APA would render 17 U.S.C. § 701(e) superfluous. JA52.

That is mistaken. Under our approach, the Library qualifies as an “agency” whose final actions are subject to Section 702 judicial review *only* when it is carrying out purely executive functions that cannot be exercised by “the Congress.” In contrast, 17 U.S.C. § 701(e) makes the Copyright Office subject to APA review for *any and every* final action it takes, regardless of the nature of the action. For instance, it makes the Copyright Office’s employment decisions subject to APA review. *See Carducci v. Regan*, 714 F.2d 171, 174 n.1 (D.C. Cir. 1983) (“This court had frequently reviewed [even] minor personnel actions. . . under the judicial review provisions of the APA.”). But the same is not so of the Library. *See Clark*, 750 F.2d at 102 (no APA review of the Library’s personnel decisions).

Under our reading of the relevant statutory provisions, then, Section 701(e) does substantial work by expanding significantly the range of routine decisions of the Copyright Office that are subject to judicial review under the APA. And courts should “not hesitate to give effect to two statutes that overlap,

so long as each reaches some distinct cases.” *J.E.M. Ag Supply v. Pioneer Hi-Bred International*, 534 U.S. 124, 144 (2001).

If anything, 17 U.S.C. § 701(e) lends further support to *our* arguments. First, it confirms that the Congress understands the hybrid nature of the Library, which sometimes exercises executive authority. Aside from that, all of the rulemaking documents, including the Library’s ultimate approval of the Register’s recommendation, are published in the Federal Register under the name of both the Library *and* the Copyright Office. *See JA67, 72, 90, 92.* Viewed through the lens of 17 U.S.C. § 701(e), this suggests that Congress intended the rulemaking to be reviewable under the APA.

4. *The relevant canons of construction resolve any ambiguity in favor of judicial review*

The text of the relevant statutes makes clear that APA review is available in these circumstances. But even if there were any ambiguity remaining, two canons of statutory construction compel construing the Library’s final action here to be the final action of an “agency” within the meaning of the APA.

a. Presumption in favor of judicial review. “Consider first ‘a familiar principle of statutory construction: the presumption favoring judicial review of administrative action.’” *Guerrero-Lasprilla v. Barr*, 140 S. Ct. 1062, 1069 (2020) (quoting *Kucana v. Holder*, 558 U.S. 233, 251 (2010)).

As federal agencies have assumed increasing prominence in the federal legal landscape, the Supreme Court has repeatedly endorsed the “strong presumption favoring judicial review of administrative action.” *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 486 (2015); *see also Sackett v. EPA*, 566 U.S. 120, 128-129 (2012); *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986). It has stressed that “Congress rarely intends to prevent courts from enforcing its directives to federal agencies,” and that an official federal defendant like the Library “bears a ‘heavy burden’ in attempting to show that Congress prohibit[ed] all judicial review of [its] compliance with a legislative mandate.” *Mach Mining*, 575 U.S. at 486 (quotation marks omitted).

“The presumption can only be overcome by ‘clear and convincing evidence’ of congressional intent to preclude judicial review.” *Guerrero-Lasprilla*, 140 S. Ct. at 1069 (quoting *Reno v. Catholic Social Services*, 509 U.S. 43, 64 (1993)); *accord Bowen*, 476 U.S. at 671 (stating the same and quoting from the APA’s legislative history). This Court has characterized the canon as a “clear statement” rule. *Knapp Medical Center v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017).

There is no “clear and convincing evidence” or “clear statement” here to suggest that the drafters of the APA intended to exempt the Library of Congress from judicial review when it is engaged in a traditional notice-and-comment rulemaking under the DMCA.

As a starting point, Congress knows how to supply clear statements of such an intent, and it does so routinely. It has stated plainly, for example, that no action of an agency under the Congressional Review Act is subject to challenge in court. *See* 5 U.S.C. § 805 (“No determination, finding, action, or omission under this chapter shall be subject to judicial review.”). And it sometimes determines that the APA should not apply to certain agencies altogether, specifying, for example, that “the provisions of chapters 5 and 7 of title 5, shall [not] apply to the exercise of the powers of the Postal Service.” 39 U.S.C. § 410(a). But there is no similar clear statement concerning the Library—at most, there is a silent implication that the Library might in some circumstances count as a component of “the Congress.”

That is not enough. The starting point, under the canon, is to presume that Congress intended to provide for judicial review, and to ask whether there is a clear and affirmative statement that Congress meant to withdraw that right. Critically, “the ‘well-settled’ and ‘strong presumption’ in favor of judicial review is so embedded in the law that it applies even when determining the scope of statutory provisions specifically designed to limit judicial review,” meaning that it “‘applies even where, as here, the statute expressly prohibits judicial review’” in particular circumstances. *Make the Road New York v. Wolf*, 962 F.3d 612, 624 (D.C. Cir. 2020) (quoting *Guerrero-Lasprilla*, 140 S. Ct. at 1069 and *El Paso Natural Gas Co. v. United States*, 632 F.3d 1272, 1276 (D.C.

Cir. 2011)). “[I]n other words, the presumption dictates that such provisions must be read narrowly.” *Id.* (quoting *El Paso*).

The district court, having elided our textual arguments, wrongly concluded that the words “the Congress” plainly cover the “Library of Congress” in all contexts and scenarios. But it did so without even considering whether the words “the Congress” could plausibly be read more narrowly, so as to exclude (or, conversely, whether the word “agency” could be read more broadly, so as to include) the Library when it is engaged in executive rulemakings. As we have shown, it not only *can* be so read, but it *must* be. The district court’s disregard for the canon in favor of judicial review was unjustifiable.

The district court was also wrong to suggest that the presumption may be set aside because it is possible that aggrieved parties may bring *ultra vires* actions under the *Larson* doctrine. *See* JA55-56 n.6. The same has been true in every case in which this Court or the Supreme Court has previously relied on the presumption in favor of judicial review—*ultra vires* actions are always theoretically available. But that truism did not factor into the Supreme Court’s observation in *Sackett*, for example, that the APA “creates a ‘presumption favoring judicial review of administrative action,’” let alone its conclusion that “the APA’s presumption of reviewability for all final agency action” was not overcome in that case. 566 U.S. at 128-129. Nor did it factor into the pro-judicial-review outcomes of *Mach Mining*, *Guerrero-Lasprilla*, *Knapp Medical*

Center, or *Bowen*. Indeed, if it were enough to overcome the presumption in favor of judicial review to observe simply that an *ultra vires* action is theoretically available, the presumption would mean nothing.

b. Constitutional avoidance. Further tipping the scales in appellants' favor are the grave constitutional concerns lurking behind the district court's statutory construction. Under that canon, when a "serious doubt is raised about the constitutionality of an act of Congress, [courts must] first ascertain whether a construction of the statute is fairly possible by which the question may be avoided." *Nielsen v. Preap*, 139 S. Ct. 954, 971 (2019) (cleaned up). That rule further compels our reading of "agency."

The district court's holding offends the separation of powers, chiefly the rule that the legislative branch may not exercise executive authority. The Constitution divides the government's powers "into three defined categories, Legislative, Executive, and Judicial." *Free Enterprise Fund*, 561 U.S. at 483 (quoting *INS v. Chadha*, 462 U.S. 919, 951 (1983)). It allocates each governmental power exclusively to one branch, forbidding its exercise by the rest: "All legislative Powers herein granted shall be vested in a Congress of the United States" (Art. I, § 1), "[t]he executive Power shall be vested in a President of the United States" (Art. II, § 1, cl. 1), and "[t]he judicial Power of the United States, shall be vested in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish" (Art. III, § 1).

Well aware of Parliament’s abuses of power, and wary of seeing those same abuses repeated, “the Framers recognized [in particular the] danger of the Legislative Branch’s accreting to itself . . . [of] executive power.” *Mistretta v. United States*, 488 U.S. 361, 382 (1989) (citing *The Federalist No. 51*, p. 350 (J. Cooke ed. 1961)). The Constitution’s tripartite structure thus most especially “does not permit Congress to execute the laws.” *Bowsher v. Synar*, 478 U.S. 714, 726 (1986).

As the district court rightly recognized, the Library’s authority under the DMCA is executive in nature. Promulgating a regulation under statutory authority is quintessentially an “exercise[] of—[and] under our constitutional structure . . . *must* be [an] exercise[] of—the ‘executive Power’” within the meaning of Art. II, § 1, cl. 1. *City of Arlington v. FCC*, 569 U.S. 290, 304 n.4 (2013); *accord Intercollegiate*, 684 F.3d at 1342. That is precisely what the Library does under the DMCA—in adopting anticircumvention exemptions, it is “implementing [a] legislative mandate,” the *sin qua non* of executive authority. *Collins v. Yellen*, 141 S. Ct. 1761, 1785 (2021).

The upshot is obvious: The Library cannot exercise such executive authority while also assuming the character of “the Congress.”

There are two conceivable ways to read the APA’s text to “avoid” (*Nielsen*, 139 S. Ct. at 971) this constitutional problem—but only one of them is reasonable and thus compelled by the constitutional avoidance canon. *See*

Nielsen v. Preap, 139 S. Ct. at 971; *Hooper v. California*, 155 U.S. 648, 657 (1895) (“the elementary rule is that every *reasonable* construction must be resorted to in order to save a statute from unconstitutionality”) (emphasis added).

First, the Court may conclude that the drafters of the APA meant the words “the Congress” in Section 701(b)(1) to refer *not* to the branch of government established by Article I of the Constitution, but instead to some indeterminate, imaginary body that courts must define ad hoc, in litigation. Under this approach, the Court would say that there is no constitutional problem in denying judicial review under the APA here because the Library is a part of “the Congress” only in the statutory sense, not the constitutional sense. The government floated this idea below, but it did not explain why or how such an approach would make any sense.

Alternatively, the Court may conclude that when the drafters of the APA said “the Congress,” they meant *the Congress*, but that the Library does not constitute an element of “the Congress” when it is engaged in executive functions. Under this approach—the one offered by appellants—the Court would say that there is no constitutional problem because the Library, when it is engaged in executive rulemakings, appropriately operates as a component of the Executive Branch, not “the Congress.” Its executive rulemakings are therefore subject to judicial review under Section 702 of the APA.

Only the second option is a reasonable one. It would beggar belief to say that the lawmakers responsible for enacting the APA, when they said “the Congress,” meant something other than the branch of government established by Article I of the Constitution. References to “Congress” appear thousands of times throughout the U.S. Code, and we are unaware of a single instance where it means anything else. *See, e.g.*, 2 U.S.C. § 1 (referring to Senators “elected to represent [each] State in Congress”); 2 U.S.C. § 7 (establishing the day of election for “Representatives and Delegates to the Congress”). The government certainly has cited none. In contrast, it is eminently reasonable to say that the Library does not constitute “the Congress” when it is engaged in an executive rulemaking that—as a constitutional matter—may only ever be undertaken by an Executive Branch agency.

The district court again did not engage with these arguments. It accepted that “[t]he Library serves both executive and legislative functions.” JA64. And it agreed the Librarian “engages in executive power under Article II when promulgating rules under the APA.” *Id.* It then observed simplistically that the Library “does not run afoul of separation of powers principles so long as both executive *and* legislative power are not simultaneously wielded.” *Id.*

That is true, but it misses the point, which is that the Library cannot exercise legislative power sometimes and executive power other times, and yet *always* qualify as an element of “the Congress.” Rather, when it is exercising

executive authority, it must be understood to be “a ‘component of the Executive Branch’” (*Intercollegiate*, 684 F.3d at 1342)—meaning it must be understood to be an executive “agency” under the APA.

B. A holding that the Library is an “agency” with respect to its DMCA rulemakings would be consistent with precedent

The district court declined to engage the substance of most of our arguments principally because it believed that “binding D.C. Circuit precedent makes crystal clear that the Library is not an ‘agency.’” JA53. But the only way to reach that conclusion is to assume that, if the Library is *ever* an element of “the Congress,” it is *always* an element of “the Congress.” That assumption (which underpinned the lower court’s decision but went entirely unacknowledged and thus unexplained) is wrong, as *Intercollegiate* teaches.

The Court’s prior cases touching on the status of the Library in other contexts are not to the contrary. To be sure, the Court said in *Clark v. Library of Congress*, 750 F.2d 89 (D.C. Cir. 1984), that “the Library of Congress is not an ‘agency’ as defined under the Administrative Procedure Act.” *Id.* at 102. But it reached that conclusion in the context of a Title VII employment dispute. Courts have concluded (rightly) that the Library “operates independently from the Executive Branch in conducting its daily operations.” *Live365 v. Copyright Royalty Board*, 698 F. Supp. 2d 25, 43 (D.D.C. 2010). In other words, the Library is a component of the Congress—and it does not act as an executive

agency—with respect to its day-to-day personnel decisions. There is thus nothing amiss with *Clark*'s holding that the Library, in the circumstances of that case, was “not an ‘agency’ as defined under the Administrative Procedure Act.” 750 F.2d at 102.

At the same time, the question presented here—whether the Library functions as an “agency” when it is engaged in administrative rulemakings—simply was not presented in or resolved by *Clark*. Indeed, the Court devoted just a single sentence to the Library’s status in that case—and it did so without even hinting at, much less resolving, the extensive textual evidence that Congress intended the Library to count as an “agency” within the meaning of Section 701(b)(1) when it is engaged in executive rulemakings that utilize the APA’s notice-and-comment procedures.²

Since *Clark*, moreover, the Court has confirmed the Library’s hybrid character in *Intercollegiate*, providing essential context for understanding *Clark*’s one-sentence holding concerning the Library’s status under the APA. In *Intercollegiate*, the Court recognized that the Librarian is a “Head of Department” within the meaning of the Appointments Clause—which is to say, it

² So too of the other cases the district court cited (JA53) to support its holding. Like *Clark*, the decision in *Ethnic Employees of Library of Congress v. Boorstin*, 751 F.2d 1405 (D.C. Cir. 1985), concerned an employment claim and did not implicate the Library’s executive powers. And *Washington Legal Foundation* did not concern the Library; it only referred to it in passing dictum. See 17 F.3d at 1449.

recognized that she heads an executive agency. 684 F.3d at 1342. And the Court explained that in some circumstances, including those at issue here, the Library “is undoubtedly a ‘component of the Executive Branch.’” *Id.* at 1341-42 (quoting *Free Enterprise Fund*, 561 U.S. at 511 (2010)).

To be clear, our position is not that *Intercollegiate* “implicitly overturned or modified” *Clark* or any other case. JA55. A reversal in this case would be compatible with *Clark*, given that *Clark* involved the Library’s legislative role, and not its executive role. Our position, instead, is only that “opinions dispose of discrete cases and controversies[,] and they must be read with a careful eye to context.” *National Pork Producers Council v. Ross*, 143 S. Ct. 1142, 1155 (2023) (citing *Cohens v. Virginia*, 6 Wheat. 264, 399-400 (1821) (Marshall, C. J.)). More simply stated, judicial opinions like *Clark* must “be read in the light of the facts of the case under discussion.” *Armour & Co. v. Wantock*, 323 U.S. 126, 133 (1944); *accord, e.g.*, *Kennedy v. United States*, 353 F.2d 462, 465 n.7 (D.C. Cir. 1965) (“Judicial opinions” must be construed with due “regard . . . to the facts before the court.”).

After *Intercollegiate*, the Court’s one-line holding in *Clark* must be read in light of the facts presented in that case, which did not involve the Library engaging in notice-and-comment rulemaking to implement a statute. Understood in this way, we submit that *Clark* remains good law as far as it goes, but that it does not resolve the question presented here.

* * *

The district court’s analysis rests on an implausible premise: the Library is a component of “the Congress” (5 U.S.C. § 701(b)(1)), regardless whether it is exercising legislative or executive authority. That view is wrong as a matter of statutory text, is inconsistent with longstanding Library practice, ignores the presumption in favor of judicial review, needlessly implicates separation-of-powers concerns, and is inconsistent with the reasoning in *Intercollegiate*. When the Library exercises executive power, as it did here, it does so as an Executive Branch “agency,” and the APA makes judicial review available.

II. ALTERNATIVELY, THE COURT SHOULD REVERSE UNDER THE LARSON DOCTRINE

The Court can and should hold that the Library’s executive rulemakings are subject to judicial review under Section 702. But even if the Court were to conclude otherwise, reversal still would be warranted.

The Supreme Court and this Court have long recognized that “sovereign immunity does not bar suits for [non-monetary] relief against government officials where the challenged actions of the officials are alleged to be unconstitutional or beyond statutory authority.” *Clark*, 750 F.2d at 102 (citing *Larson v. Domestic and Foreign Corp.*, 337 U.S. 682, 689–91 (1949) and *Dugan v. Rank*, 372 U.S. 609, 621–22 (1963)). “Review for *ultra vires* acts rests on the longstanding principle that if an agency action is ‘unauthorized by the

statute under which [the agency] assumes to act,’ the agency has ‘violate[d] the law’ and ‘the courts generally have jurisdiction to grant relief.’” *National Association of Postal Supervisors v. United States Postal Service*, 26 F.4th 960, 970 (D.C. Cir. 2022) (quoting *American School of Magnetic Healing v. McAnnulty*, 187 U.S. 94, 108 (1902)).

That describes this case: In granting the Exemption, the Librarian plainly went beyond the powers delegated to her under the DMCA. The district court’s determination that *Larson* relief is unavailable here turns on a misunderstanding of the nature and magnitude of the Librarian’s error.

Before proceeding further, however, we pause to note that the district court was in all events wrong to dismiss the case on immunity grounds. *See JA56-58*. As we explained in the Statement (*supra* at 5), “[t]here is nothing in the language of the second sentence of § 702 that restricts its waiver [of immunity] to suits brought under the APA.” *Trudeau v. FTC*, 456 F.3d 178, 186 (D.C. Cir. 2006). Thus, “the APA’s waiver of sovereign immunity applies to any suit” challenging a final agency action, “whether [it is brought] under the APA or not.” *Id.* (quotation marks omitted). It was on this ground that the Court in *Clark*—even while finding the Library not subject to judicial review under the APA in the context of that case—nonetheless proceeded to grant relief on the plaintiff’s constitutional claim.

In rejecting appellants' *Larson* claim, the district court was thus in actuality ruling on its merits. It concluded that the Library had not "acted so clearly in defiance of [the DMCA], as to warrant the immediate intervention of an equity court." JA60 (quoting *Federal Express*). We of course disagree with that holding—but setting that aside for the moment, the holding must be understood as a rejection of the claim on its own terms (a Rule 12(b)(6) dismissal), and not a finding that Section 702 of the APA did not waive the government's sovereign immunity (a Rule 12(b)(1) dismissal). That clarification aside, we turn to the nub of the issue.

A. There is no way to characterize the purely commercial uses at issue here as "fair use"

The DMCA authorizes the Librarian to promulgate exemptions to the anti-circumvention rules only when they threaten to suppress "noninfringing uses . . . of a particular class of copyrighted works." 17 U.S.C. § 1201(a)(1)(C). The Librarian's statutory authority to promulgate an exemption thus turns first and foremost on whether the proposed use is noninfringing. Promulgating an exemption for an *infringing* use, to advance separate policy reasons having nothing to do with the DMCA, would be contrary to the statute and in excess of the powers conferred by Congress.

That is just what the Librarian did. Ostensibly, she determined the ISOs' uses were noninfringing because they qualified as fair use. But on closer look,

her analysis was no fair-use analysis at all. Rather, as the Librarian admitted, she approved the Exemption because doing so would help lower prices for machine service and repairs, supporting an Executive Branch policy having nothing to do with the DMCA and directly contrary to fair use principles.

1. Congress has delineated four factors for analyzing fair use. The first factor is the “purpose and character of the use, including whether such use is of a commercial nature.” 17 U.S.C. § 107(1). This factor lies at the heart of copyright law—preventing uncompensated exploitation of proprietary material and thereby “enriching the general public through access to creative works.” *Kirtsaeng v. John Wiley & Sons, Inc.*, 579 U.S. 197, 204 (2016). The Librarian’s disregard for this objective raises a powerful inference that she did not intend to serve the goals of the DMCA or copyright at all.

There is no debate that an ISO’s use of OEM software for maintenance services is “entirely commercial in nature.” *Triad Systems v. Southeastern Express*, 64 F.3d 1330, 1337 (9th Cir. 1995) (holding that using OEM software for maintenance is not fair use); *accord Advanced Computer Services of Michigan v. MAI Systems*, 845 F. Supp. 356, 364-66 (E.D. Va. 1994) (same). Such commercial use “tends to weigh against a finding of fair use” because “the user stands to profit from exploitation of the copyrighted material without paying the customary price.” *Harper & Row Publishers, Inc. v. Nation Enterprises*, 471 U.S. 539, 562 (1985).

The Librarian brushed aside the purely commercial nature of the ISOs' intended use, stating without elaboration that their plan to compete with OEMs for maintenance contracts "is not fatal to [the] fair use determination." JA154. While true that commercial use is not singularly dispositive of a fair-use assertion, it weighs strongly against fair use when the user acts with "*the intended purpose* of supplanting the copyright holder's commercially valuable right." *Harper & Row*, 471 U.S. at 562.

Moreover, to determine whether the "commercial nature" of a use is fatal to a fair-use finding, the Library was supposed to weigh it "against the degree to which the use has a further purpose or different character." *Andy Warhol Foundation for the Visual Arts v. Goldsmith*, No. 21-869, 2023 WL 3511534, at *10 (U.S. May 18, 2023) (citing *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 579 (1994)). "[T]he more transformative the new work, the less will be the significance of other factors, like commercialism, that may weigh against a finding of fair use." *Id.* (quoting same).

On that front, the Library concluded that the ISOs' use of the software was "likely transformative." JA154. But that is clearly, unequivocally wrong.

A transformative use of a copyrighted work is one that adds "new expression, meaning or message" by altering the content, context, or presentation of the work. *Google*, 141 S. Ct. at 1202 (quoting *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 579 (1994)). It asks "whether the copier's use adds

something new, with a further purpose or different character,” thus “altering the copyrighted work” with some new and different expression. *Id.* The underlying idea is that copyright law should “promote science and the arts” and not stifle it. *Campbell*, 510 U.S. at 579.

The ISOs’ proposed uses do not meet that definition in any conceivable respect; they “simply commandeer” the copyright holder’s “software and us[e] it for the very purpose for which, and in precisely the manner in which, it was designed to be used.” *Triad Systems*, 64 F.3d at 1337. That is to say, an ISO that copies documents and code for purposes of device maintenance “invent[s] nothing of its own.” *Id.* at 1336. Allowing ISOs to copy an OEM’s code to boost their own profits thus does not promote innovation or creativity at all.

There can be no dispute about this: The ISOs themselves expressly disclaimed transformative use, explaining in their petitions that they did “not seek an exemption to modify medical devices or systems, or their software,” in any way. JA153. They wished only to copy the software and use it precisely as it was designed, angling to avoid FDA regulations. That is not a “fair” use.

2. In finding otherwise, the Librarian’s only explanation was to say that she had “previously concluded that diagnosis and repair are likely to be transformative uses” (JA156), pointing to prior rulemakings concerning exemptions for the service and repair of consumer products like cell phones and game consoles. There are two glaring problems with that extrapolation.

First, the Librarian herself acknowledged that “fair use analysis is ultimately a fact-specific inquiry that can vary based on the type of device,” and that it is not possible to make a categorical fair-use determination with respect to maintenance and repair of “all software-enabled devices.” JA147. Thus, what the Librarian reasoned or concluded in some other rulemaking, with respect to some other device category, was admittedly irrelevant to her decision in *this* rulemaking concerning complex medical devices.

Second, the prior rulemakings from which the Librarian made her inappropriate extrapolation concerned uses that all agreed *were* transformative. In particular, the 2015 rulemaking cited in the Register’s recommendation (JA156 n.1167) concerned “diagnosis, *modification*, and repair” of electronic control units (ECUs) in automobiles. *See* JA123-124 (emphasis added). The Librarian thus observed in 2015 that “copying the work” embedded in automobile ECUs would often lead to “creat[ing] new applications” and “modification of ECU computer programs” to allow new modes of “interoperat[ion]” among auto parts. JA123. She concluded, therefore, that “at least some of the proposed uses of ECU computer programs are likely to be transformative.” *Id.* Later, in the 2018 rulemaking, the Librarian cited to its 2015 analysis, but without acknowledging this crucial factor. *See* JA129-131 & nn.1254, 1262.

The Register’s analysis of ECUs in 2015 was obviously inapplicable to the rulemaking here. Again, the ISOs in this case expressly disclaimed modification

of any software code or the creation of new applications. The Librarian’s reference back to 2015 and 2018 rulemakings concerning other devices and technologies with no relation to medical devices is an abdication of her statutory duty to evaluate the facts before her.

B. The Librarian’s true rationale reflects economic policymaking that is unauthorized by the DMCA

Against this backdrop, to call the Librarian’s analysis a “fair use” analysis would elevate labels over substance. As this Court has recognized, it is enough to state an *ultra vires* claim to show that the government official’s “decision [is] so unreasonable that [she] must have used and applied criteria and reasoning that Congress did not permit in the governing statute.” *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1070 (D.C. Cir. 2018). That is the case here. In fact, the Librarian openly stated her true intentions: The Exemption was warranted, she explained, because “OEMs charge higher prices” than ISOs “to service their equipment,” creating “competitive concerns recently highlighted by the Executive Branch.” JA173.

Although the DMCA permits the Librarian to consider “other factors as the Librarian considers appropriate” when determining whether a particular noninfringing use is “adversely affected” (17 U.S.C. § 1201(a)(1)(C)), that license does not obviate a fair-use finding. And the true reason cited by the

Librarian for the Exemption—competitive concerns and high prices—is utterly anathema to such a fair-use finding.

“[C]opyright is a commercial right, intended to protect the ability of authors to profit from the exclusive right to merchandise their own work.” *Authors Guild v. Google*, 804 F.3d 202, 214 (2d Cir. 2015). Here, the Librarian improperly considered how granting the Exemption would improve competition with copyright holders and thus lower prices, even though the central purpose of copyright laws is to stimulate creativity by *protecting* the right of producers of copyrightable work to recoup the expense of their creative labors.

Indeed, the fourth fair-use factor calls for consideration of “the effect of the use upon the potential market for or value of the copyrighted work.” 17 U.S.C. § 107(4). This factor “requires courts to consider not only the extent of market harm caused by the particular actions of the alleged infringer, but also whether unrestricted and widespread conduct of the sort engaged in by the [user] would result in a substantially adverse impact on the potential market for the original.” *Campbell*, 510 U.S. at 590 (cleaned up). In evaluating this factor, courts “must take account not only of harm to the original but also of harm to the market for derivative works.” *Harper & Row*, 471 U.S. at 568.

Other courts have held that “[b]ecause [an ISOs’ use of] software [is] commercial . . . the likelihood of future harm to the potential market for or to the value of the software may be presumed.” *Advanced Computer Services*, 845

F. Supp. at 364-66. That is because it “likely cause[s] a significant adverse impact on [OEMs’] licensing and service revenues and lower returns on its copyrighted software investment” for ISOs to “freely use[] . . . copyrighted software on a widespread basis to compete with” OEMs for service and maintenance contracts. *Triad Systems*, 64 F.3d at 1337.

These points were brought to the Librarian’s attention, but rather than explaining how harm to the market could be overcome, she cited harm to the commercial interests of the copyright holders as a *feature* of her reasoning. She observed “that medical service providers must spend more to service their equipment” if they use OEM services “than if they were able to . . . have an ISO perform repairs on their behalf.” JA173. In her view, granting the Exemption would thus “help to address the broader competitive concerns.” *Id.*

Such open disregard for Congress’s instruction moves the Librarian’s actions beyond merely “a claim of error in the exercise of the power” (*Doehla Greeting Cards v. Summerfield*, 227 F.2d 44, 46 (D.C. Cir. 1955)) to an assertion of policymaking authority “in excess of [her] delegated powers and contrary to” the DMCA’s express limits (*Aid Association for Lutherans v. U.S. Postal Service*, 321 F.3d 1166, 1173 (D.C. Cir. 2003) (quoting *Leedom v. Kyne*, 358 U.S. 184, 188 (1958))). Although thinly veiled as a fair-use analysis, the Librarian’s reasoning in fact reflects nothing more than naked economic policymaking that turns the purpose of copyright on its head.

Ultimately, the Librarian has no authority under the DMCA to grant the Exemptions for plainly infringing uses on the basis of policy considerations unmoored from the fair-use doctrine. For this reason, the Librarian exercised power in excess of a specific limitation of her delegated authority, and the Exemption should be reviewed, and ultimately set aside, as *ultra vires*.

CONCLUSION

The Court should reverse and remand with instructions to resolve MITA and AdvaMed's APA claims on their merits or to vacate the Exemption.

June 2, 2023

Respectfully submitted,

/s/ Michael B. Kimberly

PETER TOLSDORF
*National Electrical
Manufacturers Association*
1300 17th Street North, No. 900
Arlington, VA 22209
(703) 841-3200
*Counsel for Medical Imaging &
Technology Alliance*

MICHAEL B. KIMBERLY
ALEX C. BOOTA
EMMETT WITKOVSKY-ELDRED
McDermott Will & Emery LLP
500 N. Capitol Street NW
Washington, DC 20001
mkimberly@mwe.com
(202) 756-8000
Counsel for all appellants

TERRY CHANG
*Advanced Medical
Technology Association*
1301 Pennsylvania Ave. NW
Suite 400
Washington, DC 20004
(202) 783-8700
*Counsel for Advanced Medical
Technology Association*

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1), undersigned counsel for appellants certifies that this brief:

- (i) complies with the type-volume limitation of Rule 32(a)(7)(B) because it contains 11,988 words, including footnotes and excluding the parts of the brief exempted by Rule 32(f); and
- (ii) complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it is typeset in Century Supra font in 14 points.

June 2, 2023

/s/ Michael B. Kimberly

CERTIFICATE OF SERVICE

Undersigned counsel for appellants certifies that on June 2, 2023, the foregoing document was served electronically via the Court's CM/ECF system upon all counsel of record.

June 2, 2023

/s/ Michael B. Kimberly

ADDENDUM

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Excerpts from the Administrative Procedure Act

5 U.S.C. § 551 – Definitions

...

(5) “rule making” means agency process for formulating, amending, or repealing a rule;

...

5 U.S.C. § 553 – Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

- (1)** a military or foreign affairs function of the United States; or
- (2)** a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

- (1)** a statement of the time, place, and nature of public rule making proceedings;
- (2)** reference to the legal authority under which the rule is proposed; and
- (3)** either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

- (A)** to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or
- (B)** when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

- (1)** a substantive rule which grants or recognizes an exemption or relieves a restriction;
- (2)** interpretative rules and statements of policy; or
- (3)** as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

...

5 U.S.C. § 701 – Application; definitions

...

(b) For the purpose of this chapter—

(1) “agency” means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, but does not include—

- (A)** the Congress;
- (B)** the courts of the United States;
- (C)** the governments of the territories or possessions of the United States;
- (D)** the government of the District of Columbia;

- (E) agencies composed of representatives of the parties or of representatives of organizations of the parties to the disputes determined by them;
- (F) courts martial and military commissions;
- (G) military authority exercised in the field in time of war or in occupied territory; or
- (H) functions conferred by sections 1738, 1739, 1743, and 1744 of title 12; subchapter II of chapter 471 of title 49; or sections 1884, 1891-1902, and former section 1641(b)(2), of title 50, appendix; [1] and

...

5 U.S.C. § 702 – Right of review

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party. The United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: Provided, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance. Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.

Excerpts from The Federal Register Act

44 U.S.C. § 1501 - Definitions

As used in this chapter, unless the context otherwise requires—

“document” means a Presidential proclamation or Executive order and an order, regulation, rule, certificate, code of fair competition, license, notice, or similar instrument, issued, prescribed, or promulgated by a Federal agency;

“Federal agency” or “agency” means the President of the United States, or an executive department, independent board, establishment, bureau, agency, institution, commission, or separate office of the administrative branch of the Government of the United States but not the legislative or judicial branches of the Government;

...

44 U.S.C. § 1510 - Code of Federal Regulations

(a) The Administrative Committee of the Federal Register, with the approval of the President, may require, from time to time as it considers necessary, the preparation and publication in special or supplemental editions of the Federal Register of complete codifications of the documents of each agency of the Government having general applicability and legal effect, issued or promulgated by the agency by publication in the Federal Register or by filing with the Administrative Committee, and are relied upon by the agency as authority for, or are invoked or used by it in the discharge of, its activities or functions, and are in effect as to facts arising on or after dates specified by the Administrative Committee.

(b) A codification published under subsection (a) of this section shall be printed and bound in permanent form and shall be designated as the “Code of Federal Regulations.” The Administrative Committee shall regulate the binding of the printed codifications into separate books with a view to practical usefulness and economical manufacture. Each book shall contain an explanation of its coverage and other aids to users that the Administrative Committee may require. A general index to the entire Code of Federal Regulations shall be separately printed and bound.

(c) The Administrative Committee shall regulate the supplementation and the collation and republication of the printed codifications with a view to keeping the Code of Federal Regulations as current as practicable. Each book shall be either supplemented or collated and republished at least once each calendar year.

(d) The Office of the Federal Register shall prepare and publish the codifications, supplements, collations, and indexes authorized by this section.

(e) The codified documents of the several agencies published in the supplemental edition of the Federal Register under this section, as amended by documents subsequently filed with the Office and published in the daily issues of the Federal Register shall be *prima facie* evidence of the text of the documents and of the fact that they are in effect on and after the date of publication.

...

Excerpt from The Digital Millennium Copyright Act**17 U.S.C. § 1201 - Circumvention of copyright protection systems****(a) Violations Regarding Circumvention of Technological Measures.—**

(1) (A) No person shall circumvent a technological measure that effectively controls access to a work protected under this title. The prohibition contained in the preceding sentence shall take effect at the end of the 2-year period beginning on the date of the enactment of this chapter.

(B) The prohibition contained in subparagraph (A) shall not apply to persons who are users of a copyrighted work which is in a particular class of works, if such persons are, or are likely to be in the succeeding 3-year period, adversely affected by virtue of such prohibition in their ability to make noninfringing uses of that particular class of works under this title, as determined under subparagraph (C).

(C) During the 2-year period described in subparagraph (A), and during each succeeding 3-year period, the Librarian of Congress, upon the recommendation of the Register of Copyrights, who shall consult with the Assistant Secretary for Communications and Information of the Department of Commerce and report and comment on his or her views in making such recommendation, shall make the determination in a rulemaking proceeding for purposes of subparagraph (B) of whether persons who are users of a copyrighted work are, or are likely to be in the succeeding 3-year period, adversely affected by the prohibition under subparagraph (A) in their ability to make noninfringing uses under this title of a particular class of copyrighted works. In conducting such rulemaking, the Librarian shall examine—

- (i)** the availability for use of copyrighted works;
- (ii)** the availability for use of works for nonprofit archival, preservation, and educational purposes;
- (iii)** the impact that the prohibition on the circumvention of technological measures applied to copyrighted works has on criticism, comment, news reporting, teaching, scholarship, or research;

(iv) the effect of circumvention of technological measures on the market for or value of copyrighted works; and

(v) such other factors as the Librarian considers appropriate.

(D) The Librarian shall publish any class of copyrighted works for which the Librarian has determined, pursuant to the rulemaking conducted under subparagraph (C), that noninfringing uses by persons who are users of a copyrighted work are, or are likely to be, adversely affected, and the prohibition contained in subparagraph (A) shall not apply to such users with respect to such class of works for the ensuing 3-year period.

(E) Neither the exception under subparagraph (B) from the applicability of the prohibition contained in subparagraph (A), nor any determination made in a rulemaking conducted under subparagraph (C), may be used as a defense in any action to enforce any provision of this title other than this paragraph.

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Excerpt from 37 C.F.R. § 201.40—
Exemptions to prohibition against circumvention

...

(b) Classes of copyrighted works.

...

(15) Computer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system. For purposes of this paragraph (b)(15):

- (i)** The “maintenance” of a device or system is the servicing of the device or system in order to make it work in accordance with its original specifications and any changes to those specifications authorized for that device or system; and
- (ii)** The “repair” of a device or system is the restoring of the device or system to the state of working in accordance with its original specifications and any changes to those specifications authorized for that device or system.

...

17 U.S.C. § 107 – Limitations on exclusive rights: Fair Use

Notwithstanding the provisions of sections 106 and 106A, the fair use of a copyrighted work, including such use by reproduction in copies or phonorecords or by any other means specified by that section, for purposes such as criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research, is not an infringement of copyright. In determining whether the use made of a work in any particular case is a fair use the factors to be considered shall include—

- (1)** the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;
- (2)** the nature of the copyrighted work;
- (3)** the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
- (4)** the effect of the use upon the potential market for or value of the copyrighted work.

The fact that a work is unpublished shall not itself bar a finding of fair use if such finding is made upon consideration of all the above factors.